UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ALYSSA OSOS,

Plaintiff,

v.

Case No. 23-cv-12331
Honorable Linda V. Parker

NUVASIVE, INC.

Defendant.

_____/

OPINION AND ORDER DENYING DEFENDANT'S MOTION TO DISMISS (ECF NO. 3.)

This case arises from a medical device implanted in Plaintiff Alyssa Osos' ("Osos") lower extremity, which allegedly caused severe medical issues, requiring the device's removal. (ECF No. 1.) Defendant NuVasive, Inc. is the manufacturer of the device. (*Id*. at PageID. 11.) Alleging that the device generated chromium toxicity or heavy metal poisoning which injured her, Osos filed a Complaint against NuVasive in state court, which NuVasive removed to federal court based on diversity jurisdiction. (*Id*.) In the Complaint, Osos asserts the following claims: (I) negligent production; (II) breach of implied warranty; (III) gross negligence/actual knowledge; and (IV) failure to warn. (*Id*.)

The matter is presently before the Court on NuVasive's motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). (ECF No. 3 at PageID. 61.) NuVasive argues that Osos has not stated sufficient facts to support her claims and that the "learned intermediary doctrine" precludes her failure to warn claim. (*Id*. at PageID. 61-66.) This Court is denying NuVasive's motion as to Osos' negligent production, breach of implied warranty, and gross negligence claims, and is denying the motion without prejudice as to Osos' failure to warn claim.

Standard of Review

A motion to dismiss tests the initial legal sufficiency of the complaint. *RMI Titanium Co. v. Westinghouse Elec. Corp.*, 78 F.3d 1125, 1134 (6th Cir. 1996). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

To evaluate a motion to dismiss under *Twombly*, the court must first accept the complaint's factual allegations as true. *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). The Supreme Court noted in *Iqbal* that "while legal conclusions can provide the complaint's framework, they must be supported by factual allegations." *Iqbal* 556 U.S. at 664. To survive a motion to dismiss, the allegations must "do more than create speculation or suspicion of a legally

cognizable cause of action; they must show entitlement to relief." *League of United Latin Am. Citizens v. Bredesen*, 500 F.3d 523, 527 (6th Cir. 2007) (citing *Twombly*, 550 U.S. at 555-56).

Statement of Facts

NuVasive is a medical device company that manufactures implants to treat musculoskeletal medical conditions, including limb length discrepancy. (ECF No. 1 at PageID. 10.) Since 2011, the Precice limb lengthening system was the most frequently applied lengthening device for leg length discrepancy. (*Id*. at PageID. 11.) Around 2018, Dr. Dror Paley invented the Precice Stryde limb lengthening device ("the Stryde nail"), and NuVasive manufactured the Stryde nail out of BioDur 108 stainless steel. (*Id*. at PageID. 12.)

Osos was born with a birth defect requiring leg lengthening surgery at ages four and eleven. (ECF No. 1 at PageID. 12.) Even after these surgeries, Osos' tibia (shinbone) was still two inches too short, so Dr. Paley implanted the Stryde nail in Osos in July 2020. (*Id*.) In November 2020, Osos experienced heavy menstrual bleeding and reproductive organ pain. (*Id*.) Towards the end of November, an ultrasound allegedly showed a large cyst on Osos' right ovary. (*Id*. at PageID. 13.)

On March 2, 2021, Dr. Paul Fortin, of Michigan Orthopedic Surgeons, examined Osos and determined the Stryde nail had failed. (ECF No. 1 at

PageID. 13.) Osos was instructed to use crutches to avoid stress fracture due to this failure. (*Id*. at PageID. 13-14.) Subsequently, she lost months of physical therapy progress. (*Id*.) Osos required revision surgery to remove the failed Stryde nail, after which x-rays revealed leftover fragments around the implantation site and surrounding tissues. (*Id*. at PageID. 16.) Three follow-up appointments revealed that Osos suffered from toxic chemicals in her liver, bone damage to her tibia, and chromium toxicity in her blood. (*Id*. at PageID. 17.)

On February 20, 2021, NuVasive issued an urgent recall notification on certain Precice devices, as it had received reports of the devices causing negative health impacts, such as bony abnormalities and device corrosion. (ECF No. 1 at PageID. 13.) The next month, The Paley Institute emailed a statement about the NuVasive recall to current and former patients. (*Id*. at PageID. 14.) On July 18, 2021, the U.S. Food and Drug Administration warned the public of potential problems with NuVasive Precice devices used to treat limb length discrepancy. (*Id*.) These problems included pain and abnormalities in the areas in contact with the Stryde nail, the same areas Osos experienced pain and bony abnormalities. (*Id*.)

Analysis

Sufficiency of Alleged Facts: Negligent Production, Breach of Implied Warranty, and Failure to Warn

NuVasive argues that Osos does not state sufficient facts to support her claims of negligent production (Count I), breach of implied warranty (Count II), and failure to warn (Count IV). (ECF No. 3 at PageID. 52, 65.) NuVasive focuses on the lack of factual allegations within the paragraphs discussing each specific count. Because Osos incorporates the facts set forth earlier in her Complaint in each count and these facts are sufficient to support her claims, the Court concludes that Osos has pled sufficient facts to support Counts I, II, and IV.

In Michigan, negligence and breach of implied warranty claims are distinct causes of action. Negligence claims depend upon a showing that the defendant's conduct was unreasonable, while implied warranty claims focus on "the fitness of the product, irrespective of the defendant's conduct." *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 185 (Mich. 1985). To establish a prima facie case of negligent production under Michigan law, the plaintiff must prove "(1) the product was defectively manufactured, (2) the product reached the plaintiff in the same condition that it was in when it left the manufacturer, and (3) the defect proximately caused the plaintiff's injury." *Genaw v. Garage Equip. Supply Co.*, 856 F. App'x 23, 26 (6th Cir. 2021) (citing *Prentis*, 365 N.W.2d at 187). To establish an implied warranty claim, the plaintiff must show that the product was

"transferred from the manufacturer's possession while in a 'defective' state[,]" and that the defect resulted in personal injury or property damage. *Piercefield v. Remington Arms Co.*, 133 N.W.2d 129, 134 (Mich. 1965) (alteration added).

NuVasive argues that Osos pleads the elements of her claims "in conclusory fashion without supporting facts." (ECF No. 3 at PageID. 63.) NuVasive contends that, on the negligent production claim, none of Osos' "smattering of random facts . . . are tethered to any legal cause of action." (*Id*).) NuVasive further asserts that Osos' breach of implied warranty claim is limited to "a piddly one paragraph" that lacks facts to survive a pleading challenge. (*Id*. at PageID. 64.)

NuVasive makes these assertions by citing isolated sentences contained in each count of the Complaint. (ECF No. 3 at PageID. 64 (citing ECF No. 1 at PageID. 18-19.).) The Complaint, however, incorporates the factual allegations into each count by introducing each section with: "Plaintiff, by reference, incorporates the preceding paragraphs as though fully set forth herein." (ECF No. 1 at PageID. 18-20.) The facts asserted support Osos' claims, given reasonable inferences.

Furthermore, NuVasive argues that the Complaint fails to describe the specific defect in the Stryde nail or what failure of manufacturing caused the defect. NuVasive analogizes this case to *Buhland v. Federal Cartridge Co. Inc.*, No. 1:12-cv-244, 2013 WL 12085097 (W.D. Mich. May 9, 2013). (ECF No. 3 at

PageID. 63.) In *Buhland*, the plaintiff asserted *inter alia* a negligence claim against the manufacturer of ammunition used in a firearm based on the mere fact that, as a bullet was being chambered, the gun exploded in the plaintiff's face. *Id.* at *2. The court held that the plaintiff's allegations were insufficient under *Twombly* and *Iqbal* because there were no facts explaining how the defendant's "actions in designing [the product], testing it, developing, manufacturing, [or] assembling it . . . could have been negligent." *Id.* The present matter is distinguishable because, as Osos points out in her response brief, she alleges more facts to establish NuVasive's liability. (ECF No. 5 PageID. 79.) Osos alleges flaws in the choice of metal for the nail and the FDA's concerns about the product, facts that, with reasonable inferences, support Osos' claims. (*Id*.)

Moreover, in *Genaw*, the Sixth Circuit found that Michigan law does not require that plaintiffs allege a specific defect to show causation in product liability cases where there is "a demonstrable malfunction" of the product. 856 F. App'x at 23 (citing *Holloway v. Gen. Motors Corp. Chevrolet Div.*, 271 N.W.2d 777 (Mich. 1978)). Therefore, Osos need not describe the alleged defect in detail, as the element at issue is not "how the defect was caused, but [] whether the defect caused the injury." *Id*. at 27 (alteration added).

NuVasive's argument that Osos fails to allege sufficient facts on the failure to warn claim is unpersuasive for the same reasons. Specifically, NuVasive asserts

that Osos recites, within the claim itself, only "the barest of elements alleging a failure to warn." (*Id.*) In Count IV, however, Osos also incorporates the facts previously alleged in the Complaint, from which reasonable inferences could be made to plausibly support this cause of action.

Gross Negligence

NuVasive seeks to dismiss Osos' gross negligence claim (Count III) but fails to articulate a reason for dismissal. (ECF No. 3.) When considering a motion to dismiss, "[a]ll federal courts are in agreement that the burden is on the moving party to prove that no legally cognizable claim for relief exists." Charles Alan Wright & Arthur R. Miller, 5A *Federal Practice and Procedure* § 1357 (3d ed. 2019). "It is not sufficient for a party to mention a possible argument in the most skeletal way, leaving the court to . . . put flesh on its bones." *McPherson v. Kelsey*, 125 F.3d 989, 995 (6th Cir. 1997). As NuVasive fails to explain why Osos' gross negligence claim fails, this Court will deny the motion to dismiss on Count III. (ECF No. 3 at PageID. 61.)

Learned Intermediary Doctrine: Failure to Warn

With respect to her failure to warn claim (Count IV), Osos also alleges that NuVasive failed to "provide effective communication . . . essential to the safe use of the product." (ECF No. 1 at PageID. 20.) Relying on *Brown v. Drake-Willock International, Ltd.*, 530 N.W.2d 510, 516 (Mich. Ct. App. 1995), NuVasive argues

that the learned intermediary doctrine relieves a manufacturer of its duty to warn if the manufacturer sells its product to sophisticated purchasers. (ECF No. 3 at PageID. 66-67.) For the following reasons, this Court has decided to certify questions on the applicability of the doctrine to the Michigan Supreme Court.

In *Smith v. E. R. Squibb & Sons, Inc.*, 273 N.W.2d 476 (Mich. 1979), the Michigan Supreme Court stated, in dicta, that "[a] manufacturer of a prescription drug has a legal duty to warn the medical profession, not the patient, of any risks inherent in the use of the drug which the manufacturer knows or should know to exist." *Id.* at 479. The Michigan Court of Appeals has since relied on *Smith*'s dictum to invoke the learned intermediary doctrine to exempt manufacturers from a duty to warn patients. *See, e.g., Reeder v. Hammond*, 336 N.W.2d 3 (1983); *Dunn v. Lederle Lab'ys*, 328 N.W.2d 576 (1982).

Federal district judges in the Eastern District of Michigan nevertheless remained unsure of whether the doctrine applies in Michigan. *See Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985) (Cohn, J.); *Grainger v. Sandoz Pharm.*, No. 79-40075 (E.D. Mich. 1979) (Newblatt, J.). To guide their decisions in those cases, they certified questions to the Michigan Supreme Court concerning whether the learned intermediary doctrine exists in Michigan, and if it does, how it applies. *In re Certified Questions from U.S. Dist. Ct. for E. Dist. of Mich., S. Div.*, 358 N.W.2d 873 (1984).

The Michigan Supreme Court responded that it would not "state a rule of law determining whether a prescription drug manufacturer has a duty to disclose prescription drug risks and potential side effects directly to the patient." *Id.* at 698. The Court further explained that its dictum in *Smith* "did not establish or represent a rule of law." *Id*. at 874. The Court concluded that "[t]he allocation of the duty to warn patients is a public policy question involving . . . the everyday practice of an essential profession. We believe that the Legislature is in a better position to allocate those duties." *Id*. (alteration added).

After receiving the Michigan Supreme Court's "answer," Judge Cohn held that the Supreme Court's deference to the legislature was "clearly excessive" and "may be discounted" to allow him to resolve the matter. *Odgers*, 609 F. Supp. at 870. With respect to oral contraceptives, Judge Cohn ultimately ruled that the manufacturer still has a duty to warn the patient. *Id*. at 878.

Judge Cohn explained that "[t]he reasoning behind the rule of the learned intermediary—the reliance placed by the patient on the physician and interference with that relationship—simply does not hold up when the drug involved is an oral contraceptive." *Id*. Just six years later, another judge evaluating the learned intermediary doctrine in an oral contraception case reached a contrary conclusion that the doctrine did not apply. *Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287, 1291 (E.D. Mich. 1991) (Feikens, J.) Judge Feikens offered little analysis,

however, to support his conclusion that the Michigan Supreme Court would recognize the learned intermediary doctrine. *Id*. at 1290.

This Court's obligation under *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938), is to determine what decision the Michigan Supreme Court would reach with respect to the learned intermediary doctrine's applicability to cases decided under Michigan law. Unlike the judges in *Odgers* and *Reaves*, this Court is not persuaded that *In re Certified Questions* signals that the Michigan Supreme Court would adopt the doctrine. The Michigan Supreme Court plainly stated that prior decisions did not create the doctrine and the Michigan Legislature was the appropriate body to do so. Regardless of whether this Court believes that to be an "excessive" or unnecessary delegation of the issue to the legislature, it is the Michigan Supreme Court's conclusion. The Michigan Legislature has yet to address the doctrine.

Forty years ago, the Michigan Supreme Court held that, if the Michigan Legislature refused to speak on the learned intermediary doctrine, the Supreme Court would "do so in a case where the factual record is fully developed, and . . . responds to all the issues implicated by the questions posed." *In re Certified Questions*, 358 N.W.2d at 874. The Michigan Supreme Court's only other mention of the doctrine since was in *Tammelin v. G.D. Searle & Co.*, 478 N.W.2d 436 (1991), where the Court held that the case did not clearly present an opportunity to

address the doctrine. The dissent in *Tammelin* pointed out the unresolved doctrine, stating "[w]e have an obligation to speak to the issue by formal opinion." *Id*. (Boyle, J., dissenting) (alteration added).

Accordingly, in a separate decision, this Court is certifying questions to the Michigan Supreme Court concerning the doctrine:

1. **Whether the Michigan Supreme Court in *In re Certified Questions* held that the learned intermediary doctrine does not exist in Michigan and will not exist until the legislature creates it, or left it for another time to decide whether Michigan follows the doctrine.**

2. **Whether, in the event the Michigan Supreme Court reserved for itself the decision to rule on the learned intermediary doctrine, the doctrine exists in Michigan and under what circumstances it applies.**

For now, this Court declines to dismiss Osos' failure to warn claim based on the learned intermediary doctrine, pending a response to the certified questions from the Michigan Supreme Court.

Conclusion

For the reasons set forth above, the Court finds that Osos pleads sufficient facts to support the claims in her Complaint. Furthermore, the Court denies without prejudice NuVasive's motion to dismiss Osos' failure to warn claim based on the learned intermediary doctrine, pending the Michigan Supreme Court's response to certified questions.

Accordingly,

IT IS ORDERED that Defendant's Motion to Dismiss (ECF No. 3.) is **DENIED**.

s/ Linda V. Parker
LINDA V. PARKER
U.S. DISTRICT JUDGE

Dated: July 30, 2024